Healthcare Analytics in Navy Medicine
Perspectives and Methods for Decision-Making

FOCUS ON PHARMACY

Improving Pharmacy Operations Through Enterprise-Wide Initiatives

Navy Pharmacy Operations supports four major initiatives that aim to improve patient experience, standardization, and optimization of pharmacy resources. This article highlights these four initiatives and was constructed from an interview with CAPT Thinh V. Ha, the Pharmacy Consultant to the Navy Surgeon General, and two technical consultants to BUMED, Ms. Nicola Hall and Mr. Scott Coflin from Deloitte Consulting LLP. CAPT Ha and his team provide technical and professional knowledge, advise on pharmacy-related matters, and make recommendations to BUMED Leadership.

Enterprise-Wide Navy Pharmacy Initiatives

Navy Pharmacy Operations are provided at inpatient and outpatient Navy medical facilities across the globe at more than 110 locations. CAPT Ha is supported by the Navy Pharmacy Advisory Board (military and civilian Pharmacists and pharmacy technicians) and Navy Medicine Regional pharmacy consultants. Navy Pharmacy works closely with the Defense Health Agency (DHA) Pharmacy Operations Division (POD) and Army and Air Force Pharmacy Consultants. Navy Pharmacy follows The Joint Commission (TJC) standards and the Institute for Safe Medication Practices guidance on safe medication practices and is recognized by leading national professional organizations – the American Pharmacists Associations (APhA) and the American Society of Health System Pharmacists (ASHP) – which present Navy Pharmacy opportunities to provide input on national issues in the pharmacy industry.

IN THIS ISSUE

Volume 6 • Issue 3

This article describes four enterprise-wide Navy Pharmacy initiatives that seek to improve pharmacy operations that align with the Navy Surgeon General's priorities and key themes: C*onvenience, Experience of Care,* and *Technology/Innovation*. The highlighted Navy Pharmacy initiatives include:

- Navy Pharmacy Standard Operating Procedures (SOPs)
- Patient Experience (PE) initiative
- Pharmacy Management Analytics Program (RxMAP)
- Supply Optimization and the Inventory Optimization Tool (IOT)

Navy Pharmacy Standard Operating Procedures (SOPs)

In response to high-level operational variance among Navy pharmacies, BUMED and Navy Pharmacy leadership identified a need for standardization across all Navy pharmacies and worked together to determine standard procedures based on best practices and policies to facilitate mission execution, promote readiness, and strengthen internal controls. Specifically, the SOPs aim to: increase military readiness, improve patient safety and experience, facilitate regulatory compliance across the enterprise, and reduce staff training time.

> *"When we began documenting thousands of pharmacy processes, we found gems hidden across the enterprise. Being able to standardize those best practices from site to site was key, and then from that, having a standardized experience for patients, and increasing regulatory compliance and overall mission readiness were key."*
> *— Ms. Nicola Hall, Deloitte Consulting LLP*

The success of the SOPs can be demonstrated in several ways. First, pharmacy staff who move from site to site (e.g., Active Duty) and new hires coming from training share a base knowledge of processes and policies. An example of a process that has been standardized is "show and tell" from pharmacy staff to patient, which now emphasizes the steps found to be important to patients, such as medication counseling, which includes removing prescriptions from the bag, describing them, and advising on any changes to the medications (e.g., color). Second, there has been an increase in TJC compliance as a result of standardizing documentation checks, clinic inspections, and providing sites standard templates to meet regulatory compliance items. Lastly, there has been measurable improvement in SOPs alignment—FY14 and FY15 utilization assessment scores were 85 percent and 95 percent, respectively.

The best practices documented in the Navy Pharmacy SOPs are implemented enterprise-wide enabling the smallest Navy pharmacies at a branch health clinic to the largest pharmacies in the medical centers to execute processes such as patient dispensing and patient interactions in the same manner. Pharmacy processes which are not applicable to 100% of the Navy Pharmacy locations, such as inpatient care capabilities and pharmacist clinical consulting in the patient-centered medical home, are also included in the SOPs as they are crucial to the Pharmacy operations and delivery of patient care. Site-level assessments and tailored training programs are conducted to facilitate adoption of Navy Pharmacy best practices, and address each site's SOPs alignment gaps. Finally, continual feedback from the field and sharing of best practices is critical in the overall success of the enterprise SOPs. Input is continually collected from end-users, and evaluated in conjunction with industry best practices and evolving policy and regulations, creating a dynamic and universally beneficial end product.

Patient Experience (PE)

Understanding that "The most important goal was that the patient's voice needed to be heard and it needed to get back to the person that could do something about it," the PE initiative aims to: improve patient experience, maintain patient safety, and reduce retail leakage. To achieve these goals, CAPT Ha and his team combined industry research with feedback from surveys and interviews of Navy Pharmacy patients and staff to develop a comprehensive, measurable definition of patient experience. Based on that definition, they evaluated patients' experiences at the pharmacy and identified four primary dimensions of patient experience for Navy Pharmacy:

- **Medication Availability**—Pharmacy delivers the quantity and type of medication requested by the patient;
- **Convenience**—Effort and time required of patients when filling a prescription is minimized;
- **Service Quality**—Staff are accessible, competent, and respectful in interactions with patients; and
- **Patient Safety**—Pharmacy operations ensure the prevention of harm to patients.

By analyzing patients' preferences, behaviors, and use of the pharmacy services across these dimensions, gaps were identified between patients' expectations and perceptions, which represented opportunities to improve service delivery and patient experience. Most notably, the team found that the most important item for patients was medication availability, not wait time. Given the subjectivity of patient experience, CAPT Ha and Ms. Hall stress the importance of managing patient expectations. For example, even if a site makes improvements to the quality of its services, there are many factors that can influence the patient's overall experience—including those outside the pharmacy's area of operation (e.g., limited parking near pharmacy, poor Wi-Fi at hospital).

To further understand patient behavior and the causes of the identified issues, and to devise improvement recommendations that will impact patients, the team developed an actionable scorecard that allows sites, on a monthly basis, to see what feedback patients provided about their experience and drill down into certain dimensions that may be impacting that experience. For example, if patients are disappointed with the overall medication availability at a specific pharmacy, the site can view more detailed metrics within each of the four dimensions, such as the what specific medications have been unavailable, to help identify potential root causes (e.g., supply issue, communication issue).

An approach was needed that validated the concepts, accounted for sites' patient needs and resource constraints, and planned for the ideal-state of the pharmacy Patient Experience recommendations. Currently, the PE initiative is implemented at multiple Military Treatment Facilities (MTFs), and will continue to roll out through February

2017. Ultimately, the lessons learned from these implementations will inform the development of an enterprise-wide PE improvement plan and the initiative will be deployed to all Navy MTFs.

Pharmacy Management Analytics Program (RxMAP)

The overarching goal of RxMAP is to effectively use available data to provide real-time transparency into outpatient pharmacy workflow, better manage wait times, and improve patient experience through advanced analytical modeling techniques and data visualization. RxMAP consists of three pharmacy solutions, or dashboards, which utilize underlying data capture standardization practices, usage guidelines, and governance that work together to: enable predictive analytics and standardized reporting, increase operational efficiency, and improve patient experience. These include:

- **Patient Information Center (PIC)**—Provides patients with improved information availability in pharmacy waiting areas (e.g., predicted wait times, ticket/prescription status tracking and updates of any delays or problems) to guide them through check-in and pick-up processes and provide channels for pharmacies to communicate key information at various points throughout their visit;
- **Performance Management (PM)**—Provides pharmacy site leaders and frontline staff with real-time data, forward looking predictions and historical analysis to increase insight into operations (e.g., minute-by-minute updates on how many patients are in the waiting area and their step in the prescription filling process) to better monitor and manage performance to optimize workflow and improve staff coordination and wait time; and
- **Retrospective Analytics Reporting (RAR)**—Provides pharmacy leadership with standardized, consolidated, easy to digest metrics and reports to monitor site performance through key performance indicators (e.g., wait times, productivity, case look-ups), measure pharmacy trends and assist with building business cases.

RxMAP provides patients with a consistent pharmacy experience and accurate wait time information that allows for setting manageable patient expectations. Recognizing that it is difficult for beneficiaries to have to learn a new process each time they switch MTFs, RxMAP aims to standardize the pharmacy process and, in turn, improve the patient experience. To illustrate the PIC, a patient would find the same kiosk with identical options across pharmacies enabling quick navigation (e.g., for a prescription refill). Also, by deploying enhanced predictive analytics with PM and RAR, RxMAP increases operational efficiency by enabling pharmacy staff and leadership to anticipate workload and predict when and where wait times will fluctuate to make data-driven decisions, identify bottlenecks before they arise, optimize workflows, and improve staff management (e.g., supervisor can use PM dashboard and direct personnel to different areas).

Supply Optimization and the Inventory Optimization Tool (IOT) [1]

In order to advance Navy Pharmacy towards patient demand-driven inventory practices, the IOT initiative works to: minimize excess inventory, inform supply decisions, track medication availability, and standardize data capture and procedures. Unlike commercial pharmacies, Navy pharmacies do not have a perpetual inventory system, which automatically replenishes what is dispensed. According to CAPT Ha and his colleagues, addressing this is crucial to pharmacy operations from a medication supply perspective. Without the CHCS system's dispensing being tied to the ordering system, it is difficult for pharmacy supply staff to know what should be kept on hand to meet patient needs and seasonal demands. The IOT is able to provide staff a "one-stop-shop" and inform their supply decisions by pulling in real-time, patient Rx dispensing demand data, combining reports from CHCS and DMLSS, and tracking supply performance across the pharmacy. It empowers them to make proactive decisions that better align inventory levels with actual demands.

Through implementation, patient demand alignment levels have increased—for example, a before- and after-analysis of the IOT at one site showed patient demand alignment increase from 62 percent to 74 percent—and other MTFs that have seen similar or higher increases. The IOT has already been implemented at ten sites and five additional sites are planned by February 2017; the goal is for the IOT to be rolled out throughout the enterprise to all sites by the end of February 2019.

Impact Beyond Navy Pharmacy

Outside of Navy Medicine, the Navy Pharmacy leaders present best practices on these initiatives at the annual

1 A Microsoft Excel-based decision support tool

Joint Federal Pharmacy Seminar (JFPS), which is attended by DHA, all the Services, the VA, and the industry. The Patient Experience initiative has been recognized by the APhA and adopted by a DHA Patient Experience sub-workgroup looking to adapt the initiative across the MHS enterprise.

Information for this article was constructed by Dr. Allison Russo, Ms. Sarah Irie, and Ms. Veronika Badurova (Kennell and Associates) from an interview with CAPT Thinh V. Ha (BUMED), Ms. Nicola Hall (Deloitte), and Mr. Scott Coflin (Deloitte).

SKILLS AND METHODS

— *TFL PHARMACY PILOT*

DHA instituted a pilot program in March 2014 requiring the TRICARE for Life (TFL) population to shift their utilization of select brand-name maintenance drugs from retail pharmacies. In October 2015, the pilot was expanded to include all non-active duty beneficiaries. This section describes what information and techniques are needed to analyze the effect of the TFL Pharmacy Pilot, as well as predict the effect of the expansion to other beneficiaries.

Background Data

The first step in an analysis like this is to gather background information to get a sense of the scope of the project. Pharmacy costs make up about a quarter of the total spending in the MHS. Of that, more than half is spent on retail pharmacy, which is the most expensive source of pharmacy. This pilot targeted brand-name maintenance drugs (e.g., Nexium, used to treat acid reflux or Crestor, used to treat high cholesterol), which make up more than half of the spending on retail pharmacy. The pilot gave patients three options:

1) Switch the prescription to the generic equivalent if available. The generic equivalent of a drug is always cheaper than the brand-name, but most brand-name drugs prescribed in the MHS do not have a generic equivalent available.
2) Switch the brand-name prescription to the TRICARE Mail Order Pharmacy (TMOP) or to a Military Treatment Facility (MTF) pharmacy. Filling prescriptions in these other sources saves money for both the government and the patient.
3) Continue to fill the prescription in retail, and pay 100 percent of the cost out-of-pocket.

TRICARE released a list of medications that were included in this pilot program at: http://www.health.mil/selectdruglist.

The list is arranged by product name, which can be found in both the MHS Data Repository (MDR) and the MHS MART (M2). The brand-name maintenance drugs included in the pilot with the highest expenditures were Nexium, Namenda, Advair Diskus, Crestor, and Spiriva. However, many high expenditure drugs that would also be considered brand-name maintenance drugs, such as Revlimid, Cymbalta, Zytiga, Enbrel, and Lyrica, were not included in the pilot. Although brand-name maintenance drugs make up more than half of the spending on retail pharmacy, we found that only 59 percent of these expenses were for drugs included in TRICARE's select drug list. This limited the overall impact of the program, although the select drug list still accounted for nearly $1 billion in expenditures in FY13.

Important Considerations

A major shift in pharmacy utilization has occurred in the past five years, primarily due to changes in pharmacy copays. Before FY12, retail and TMOP prescriptions had the same copays - $3 for generic scripts and $9 for brand-name, formulary drugs. However, starting in FY12, generic drugs in TMOP became free, while the copay increased to $5 in retail. Meanwhile, copays for brand-name drugs increased in both sources. This had a dramatic impact on pharmacy utilization. From FY07-FY11, retail prescriptions were increasing by five percent per year, and TMOP prescriptions increased by eight percent per year. In FY12, retail prescriptions dropped by nine percent, while TMOP prescriptions increased by 29 percent (Figure 1).

Figure 1. Number of Prescriptions (in Millions) by Source System, FY07-FY15

Source System	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15
Retail	64	68	72	75	77	70	66	61	56
TMOP	9	10	11	11	12	16	19	22	26

A huge amount of utilization shifted from retail to TMOP and continued to shift through FY15 as the pharmacy copays continued to rise. One TFL Pharmacy Pilot effect expected was a shifting of utilization from retail to other sources, especially TMOP, but the coinciding changes in pharmacy copays had the same effect, which can make it difficult to disentangle the effects of the TFL Pharmacy Pilot.

Another trend in recent years is the availability of generic equivalents. Every year, new, patented drugs come out at the same time that patents run out for other drugs. The patented drugs have no generic equivalent and can be very expensive. Conversely, when a patent runs out and a generic equivalent becomes available, both the brand-name and generic equivalent drugs become much cheaper. For example, in FY11, Lipitor cost $125 per prescription, while in FY15, the generic equivalent (atorvastatin calcium) cost only $9 per prescription. In recent years, there seems to be a slight imbalance towards drugs going off patent, which leads to savings across the US on pharmacy spending. Meanwhile, a second effect we might expect from the TFL Pharmacy Pilot is a shifting of utilization from brand-name drugs to generic equivalents, or at least a savings on brand-name prescriptions. Evaluating both of these effects are complicated by the trend in recent years of more generic equivalents becoming available.

Finally, there are two important caveats to remember with the pharmacy data available in MDR and M2. First, manufacturer refunds are not currently reported in the data for retail pharmacies. At the end of each year, pharmaceutical companies offer refunds to DHA, which can account for up to a quarter of the original expenditure. In effect, the costs of retail pharmacy are largely overstated in the MDR and M2. Second, dispensing fees are not currently reported in the data for TMOP prescriptions. This understates the cost of TMOP prescriptions, possibly by as much as ten percent. If attempting to evaluate the savings gained by shifting utilization from retail to TMOP, the amounts calculated using MDR and M2 will overstate those savings.

Analysis Plan

Using the list of drugs provided by TRICARE and filtering to TFL beneficiaries, it is possible to pull pharmacy costs for brand-name maintenance drugs before and after the pilot was introduced on March 14, 2014. The data show a drop in retail pharmacy spending, a rise in TMOP spending, and direct care pharmacy spending remaining basically flat. There is a somewhat lengthy transition period after the pilot began, making it difficult to analyze data from FY14. Simply comparing the change in spending (by source system) between FY13 and FY15 gives the effect of the pilot. During this two-year period, retail spending shrank from over $900 million to $300 million, and TMOP spending grew from just under $600 million to nearly $900 million. The savings in retail, offset by the additional costs in TMOP, show a net savings of $300 million for the MHS.

Crucially, this result does not include refunds from manufacturers, nor does it include dispensing fees for TMOP. If retail costs are overstated by a quarter and TMOP costs understated by ten percent, the true net savings would be much lower, possibly around $120 million. Besides these considerations, there were also many other changes between FY13 and FY15. Retail pharmacy copays continued to increase relative to TMOP, encouraging a shift between the two source systems. Also, drugs that went off patent during this time period also led to additional savings unrelated to the TFL Pharmacy Pilot. However, due to the timing of the shift in utilization and the relatively small shifts in copays in this timeframe, most of the effect can be attributed to the TFL Pharmacy Pilot, but it is difficult to estimate a precise amount of savings.

Expansion of the Pilot

Starting on October 1, 2015, the terms of this pilot were expanded and made permanent for all non-Active Duty MHS beneficiaries. This population, mostly Active Duty Family Members (ADFMs) and working-age retirees and their families, tends to be a much younger population than the pilot population. Younger populations are less likely to be on maintenance medications, and indeed this population accounted for roughly half as many brand-name maintenance drugs in retail as the TFL population did prior to the pilot. At first glance, if there are half as many prescriptions affected, one could expect about half the impact of the original pilot effect, or around $60 million saved.

However, there may be significant differences between the two populations. For example, the mix of maintenance drugs could be significantly different in a younger population. ADFMs in particular may be more likely to shift their utilization to the MTF rather than TMOP, which would produce even more savings for the government and the patient. Additionally, copays continue to change,

encouraging patients to switch prescriptions from retail pharmacies. The pharmacy landscape is also changing. Nexium, the highest expenditure brand-name drug in the MHS for many years, recently went off patent. On January 26, 2015, the first generic equivalent of Nexium became available, which will lead to huge savings on maintenance drugs outside the scope of this pilot expansion.

Analyzing the impact of a program like the TFL Pharmacy Pilot is difficult. Understanding the ins and outs of a particular program can be complicated and limited by the data available and implementation environment. Understanding the implementation environment into which a pilot is rolled out is an important part of finding possible confounding factors. Finally, using the results of an analysis of a previous pilot program to predict the results of subsequent programs can be affected by differences in targeted populations, changing policies, or other operational changes that have happened in the time between roll-outs.

DATA AND INFORMATION SYSTEMS

– PHARMACY DATA AND CAVEATS

The following article provides a brief discussion of data fields, data caveats, and issues impacting pharmacy data files available in the MDR and M2.

Fields in PDTS

The Pharmacy Data Transaction Service (PDTS) data file contains pharmacy data from all sources including direct care, retail, mail order, VA, and line care pharmacy transactions. Each record represents a filled outpatient prescription. There are many common terms in the PDTS data such as Person IDs, Beneficiary Category, Deployment Information, Geography, Service Dates, Demographics, Treatment DMIS ID, and National Provider ID (NPI).

The issue date represents the date of the drug utilization review (DUR) query. This is usually the date the drug was dispensed, but may not be for refills. FY/FM are based on the issue date.

Geography related data fields are available for the patient, pharmacy, and provider (prescriber).

Source System indicates where a script was filled (such as direct care, retail, etc.) This is an important field and should be used in most data queries.

There are data fields specifically about the drug dispensed, including: national drug code (NDC), generic class, therapeutic class, product name, strength, form, quantity (number of units dispensed), days supply, refill number, and dispensed as written indicator.

The following data fields describe the pharmacy itself: Treatment DMISID, Pharmacy ID (NCPDPID), Pharmacy Name, and Pharmacy NPI.

Data fields describing the prescriber are: DEA number (typically the prescriber's NPI). Other fields such as: Ordering Site, MEPRS Code, Prof Enc Record ID exist for direct care only and only when the prescription is ordered and filled at the same CHCS host.

Data fields representing cost information are: Ingredient Cost (cost of medication), Dispensing Fee, and Full Cost (allowed amount).

Fields representing payment information are: Paid by Tricare, Paid by Patient, Paid by OHI/Medicare, Taxes, and Total Payment.

Compound Pharmacy

A compound drug is a combination of two or more drugs. These are prepared by a pharmacist for a specific patient's individual needs. Because they are not mass produced, they are typically reimbursed at billed amounts. This has led to rampant abuse in billing, peaking in FY15 and costing TRICARE over $1.5 billion (or, 15 percent of total pharmacy spending.) The government has begun prosecuting those who have defrauded the system, which is causing the billing amounts to drop to a more reasonable level (Figure 2). Compound pharmacy can be identified in the MDR using the Compound Code (COMPCODE) variable in the PDTS data file. It can also be identified in M2 by filtering PDTS data to NDC = 0.

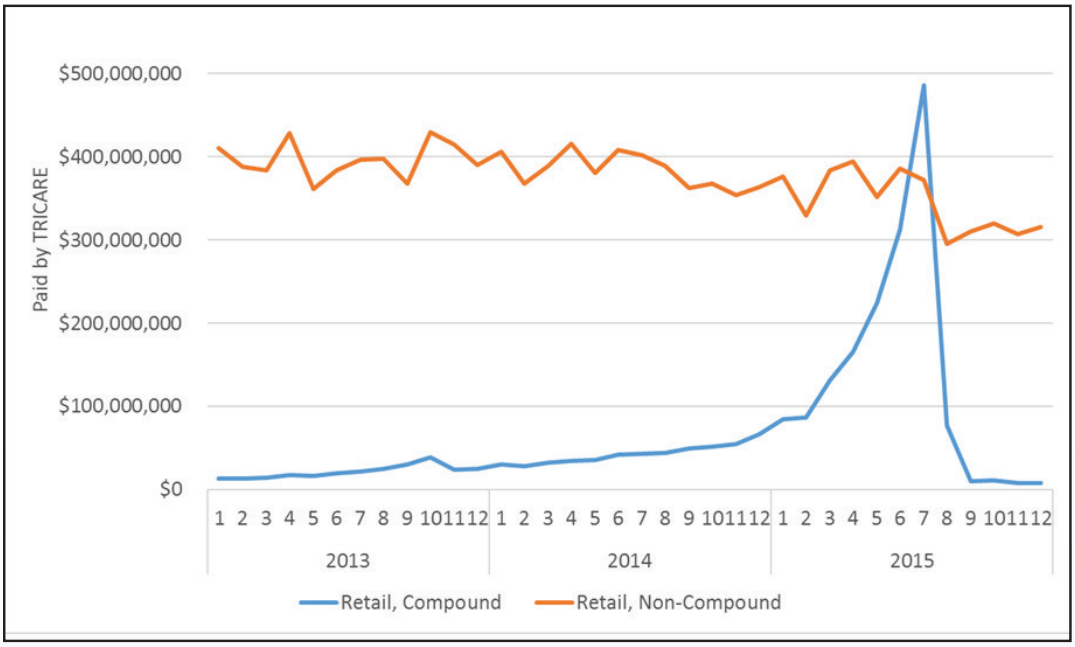
Using the NPI table to Identify Pharmacy and Ordering Physician.

Both the Pharmacy NPI and the Prescriber NPI (called DEA number) can be looked up in the NPI Directory, found in both M2 and MDR. This can be used to identify further information about the provider including name, address, and provider specialty (HIPAA taxonomy).

Clinical Data Repository (CDR) and Inpatient Pharmacy

The PDTS data file includes only outpatient dispensed prescriptions. Inpatient pharmacy is not available for

Figure 2. Growth in TRICARE Compound Pharmacy Payments, FY13-FY15



purchased care, because those drugs are covered under the DRG-based payment to the hospital. However, for direct care, there is a CDR Medications table that includes data on both inpatient medications and outpatient prescriptions. It is only available on the MDR and contains medications given to patients in the inpatient hospital setting, such as bags of fluids administered as intravenous (IV) push medications and other injectable medications. Use this file with caution, because it overlaps with PDTS data, since both data sources include outpatient direct care prescriptions.

Pharmacy Refund Data

Pharmacy refunds are being paid to the MHS to accommodate the lack of negotiated pricing in the retail pharmacy contract. These rebates are paid quarterly and lower overall purchased care pharmacy costs. However, these costs are not reflected in the PDTS data. The actual refund amount is considered sensitive data and depends on the drug, but is approximately 25 percent of the paid amount reported. Eventually, the goal is to include the amount of the refund in the PDTS data files.

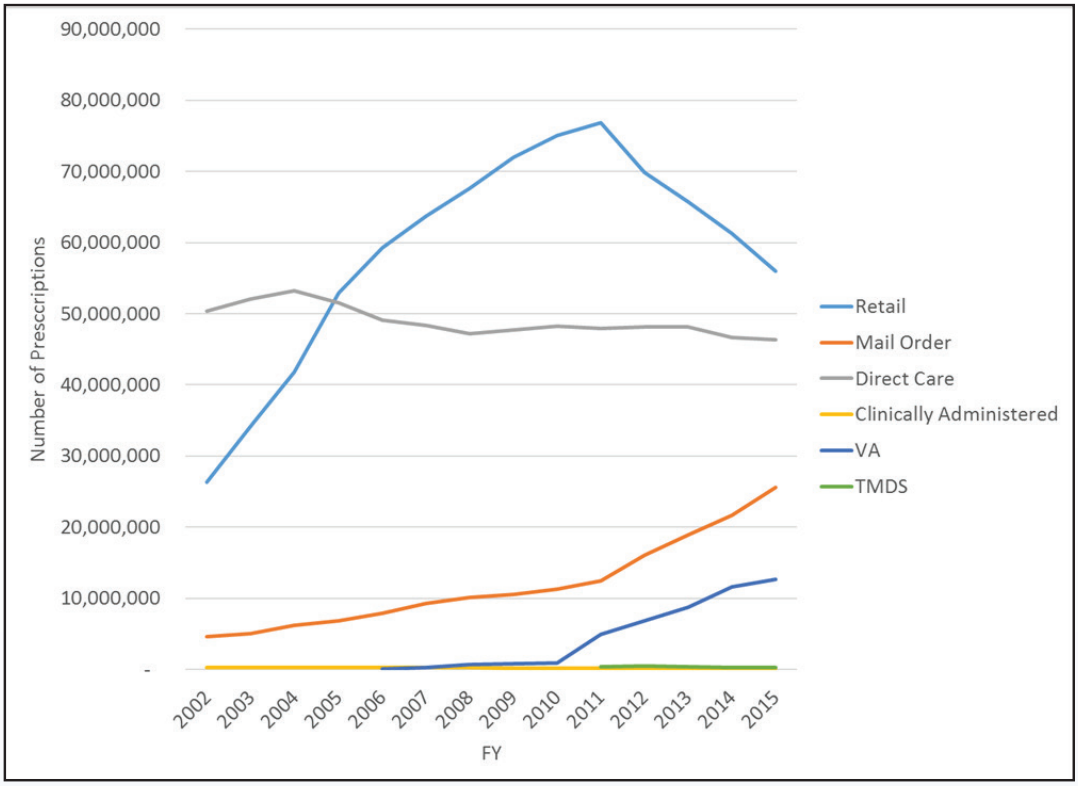
Pharmacy Copay Changes and Effects

DHA has made some benefit changes with respect to pharmacy copays. There is no copay for direct care scripts or for generic scripts filled through mail order for all beneficiaries. The copays for retail pharmacy and for brand-name drugs in mail order have increased over recent years, encouraging patients to switch to cheaper source systems. The recent copays changes are shown in Figure 3.

Figure 3. Number of Prescriptions (in Millions) by Source System, FY07-FY15

Source	Type	Before FY12	As of Oct 1, 2011	As of Feb 1, 2013	As of Feb 1, 2015
Mail Order	Generic	$3	$0	$0	$0
	Brand Formulary	$9	$9	$13	$16
	Non-Formulary	$22	$25	$43	$46
Retail	Generic	$3	$5	$5	$8
	Brand Formulary	$9	$12	$17	$20
	Non-Formulary	$22	$25	$44	$47

Figure 4. PDTS Summary: Number of Prescriptions by Source System, FY02-FY15



The result of these pharmacy copay changes has been a dramatic shift from prescriptions filled in retail pharmacy to mail order pharmacy (Figure 4). Generic drugs becoming free to the patient in mail order pharmacy also had a big impact on utilization. Although pharmacy copays are similar between mail order and retail for brand-name drugs, longer mail order scripts (usually a 90-day supply compared to a 30-day supply in retail pharmacy) represent a lower cost per day's supply for the patient.

MHS NDCs Versus Federal Drug Administration (FDA) NDCs

The FDA NDC has three segments: labeler code (4-5 digits), product code (3-4 digits), and package code (1-2 digits), and all of them separated by hyphens. The three segments can be in one of three formats: 4-4-2, 5-3-2, or 5-4-1. CMS and TRICARE both take these NDCs, pad one of the segments with zeroes, and remove the hyphens, resulting in NDCs that are always in the format 5-4-2.

For example, for a given formulation of Prozac (or fluoxetine), the NDC in the PDTS data is 00002300475. The TRICARE format is 5-4-2, so the three segments must be "00002", "3004", and "75". The only segment with a padded zero is the first, so removing that zero and adding the hyphens back in gives an FDA NDC of 0002-3004-75 (in 4-4-2 format).

How to Identify VA and Line Pharmacy

Prescriptions provided by the VA for dual-eligible beneficiaries can now be found in the PDTS data. These are identified by source system = V.

Data from the Theater Medical Data Store have also recently been added to PDTS for FY 2011 and forward. These are prescriptions provided by a line unit rather than an MTF, mail order, or retail pharmacy. These are identified by source system = R.

NEW KNOWLEDGE

– TRACKING DRUG PATENTS AND EXCLUSIVITY

In the U.S. when drugs have expiring patents or lose exclusivity, this opens the opportunity for competitors and generic manufacturers to enter the market and bring about a decrease in drug pricing. This can result in significant savings to the patient, payers, and health care systems as patients shift to less expensive generics or more compe-

tively-priced equivalents. Knowing the status of a drug's patent and/or exclusivity is often helpful in understanding and predicting drug costs within a patient population or health care system. This article explains the difference between patents and exclusivity and highlights the Federal Drug Administration's (FDA) *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the Orange Book, which is the go-to source for this type of information.

Drug patents and exclusivity work in similar ways, but they are two distinct forms of protection. Drug patents are granted by the U.S. Patent and Trademark Office to protect drug companies' investments and prevent other manufacturers from entering the market with the same product. Drug manufacturers can file for a patent at any point during the drug's development period, and a patent can encompass a wide range of claims. Exclusivity is granted by the FDA and refers to the exclusive marketing rights that the FDA gives a company upon approval of a new drug application. The idea behind exclusivity is to promote a balance between new drug innovation and generic drug competition. A patent typically expires 20 years from filing, but there are other factors that can affect a patent's duration like patent term extensions. It should be noted that the exclusivity granted to a drug after its FDA approval does not extend the patent life.

Conversely, the timing of exclusivity all depends on the type of approval. For orphan drugs, exclusivity is granted for seven years. For new chemicals, exclusivity is five years. There is also an "other" category that grants three years of exclusivity for a change, as long as the change meets certain criteria. With pediatric exclusivity, the FDA adds a period of six months on all applications held by the drug company.

Each year, the FDA publishes the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, which identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. The Orange Book also contains related patent and exclusivity information. In addition to the downloadable annual publication, providers and analysts can now also search the online Orange Book database, which contains information about approved drug products. This database allows searches by active ingredient, proprietary name, applicant, application number, dosage form, route of administration, or patent number. It is also possible to view newly added patents or delisted patents.

If you look in the Orange Book product details information under the "Patent and Exclusivity Information" link, there are "Patent Data" and "Exclusivity Data" tables. Noted in these tables are both the patent expiration and exclusivity expiration dates. Some drugs have both types of protection, and some have just one or none at all. The FDA only includes active patents and exclusivity information in the Orange Book, not those that have expired. In the online database, patent information is updated daily and exclusivity information is updated monthly.

For more information about the Orange Book and its online searchable database, please visit http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm.

The Orange Book database can be accessed directly at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

TIPS AND TRICKS

– *LINKING RX ORDERS TO FILLS USING THE DEA NUMBER IN M2*

The DEA Number in PDTS mostly contains the National Provider ID (NPI) of the ordering provider. This article provides step-by-step information on using this identifier to link prescription orders to fills in M2.

In M2, DEA Number can link the CAPER and PDTS files to examine the data at the provider level (if you want to link the CAPER encounter to what was ordered on the particular encounter use the 'Ordering Site/Prof Encounter Record' field). You can also link the DEA Number to the NPI directory in the Reference Tables, which contains comprehensive information about the provider such as full name, address, assigned DMIS ID, and up to five HIPAA taxonomies.

In the example below, we will use the DEA Number to examine which providers at a selected MTF ordered the narcotic, OxyContin. Then we will query the NPI directory only for those providers to pull their names, HIPAA taxonomies, and assigned DMIS ID information.

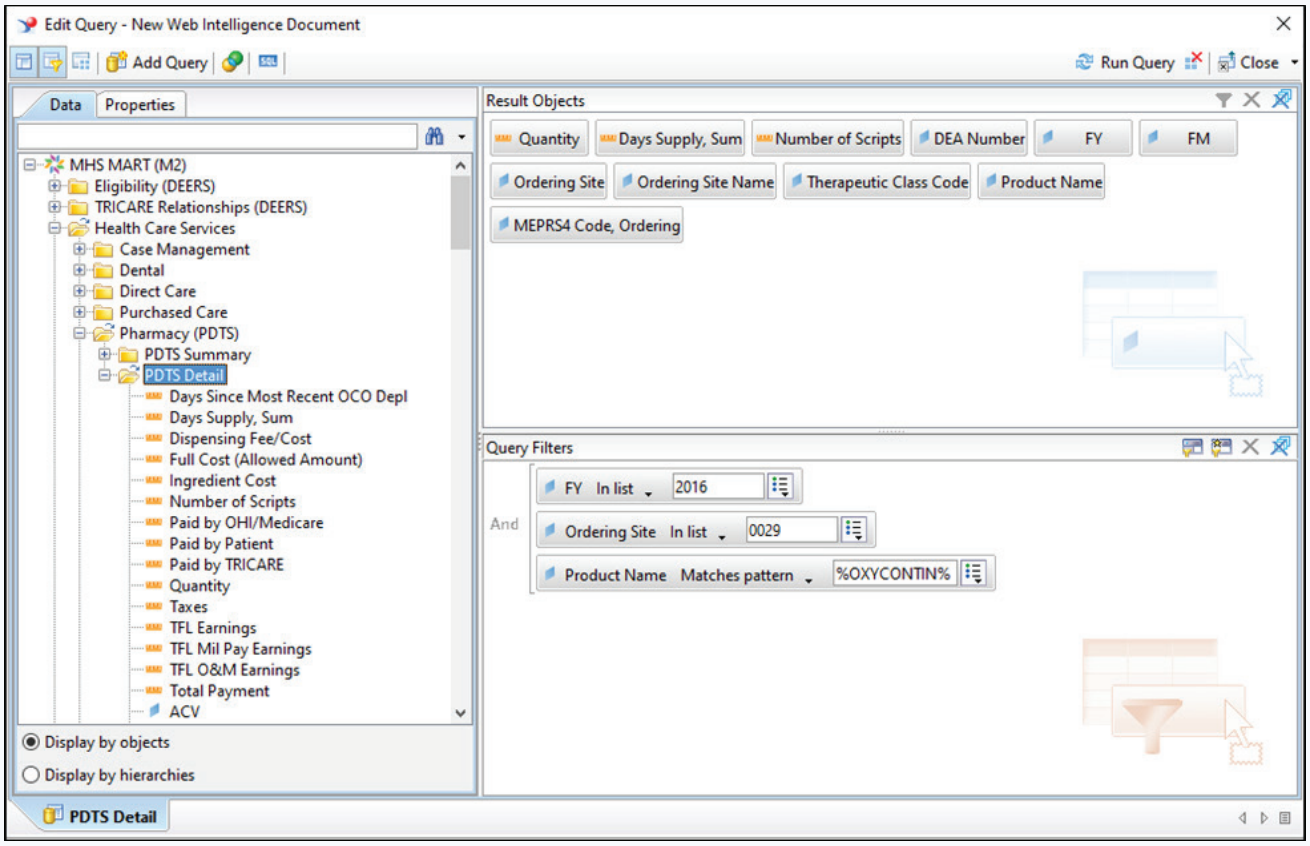
EXAMPLE - LINKING

In this example the first query will come from the PDTS Detail file (Figure 4). In the result objects include: 'Quantity', 'Days Supply, Sum', 'Number of Scripts', 'DEA Number', 'FY', 'FM', 'Ordering Site', 'Ordering Site Name', 'Therapeutic Class Code', 'Product Name', and 'MEPRS 4 Code, Ordering'.

For query filters, include 'FY in list 2016', 'Ordering Site in list 0029' (San Diego), and 'Product Name Matches Pattern %OXYCONTIN%'. The matches pattern operator, together with the percent signs, will return all product names that contain OxyContin, and as M2 is case sensitive, letters have to be in uppercase.

Select 'Run Query'.

Figure 5. PDTS Detail Query – Providers at San Diego (DMIS ID 0029) Ordering OxyContin

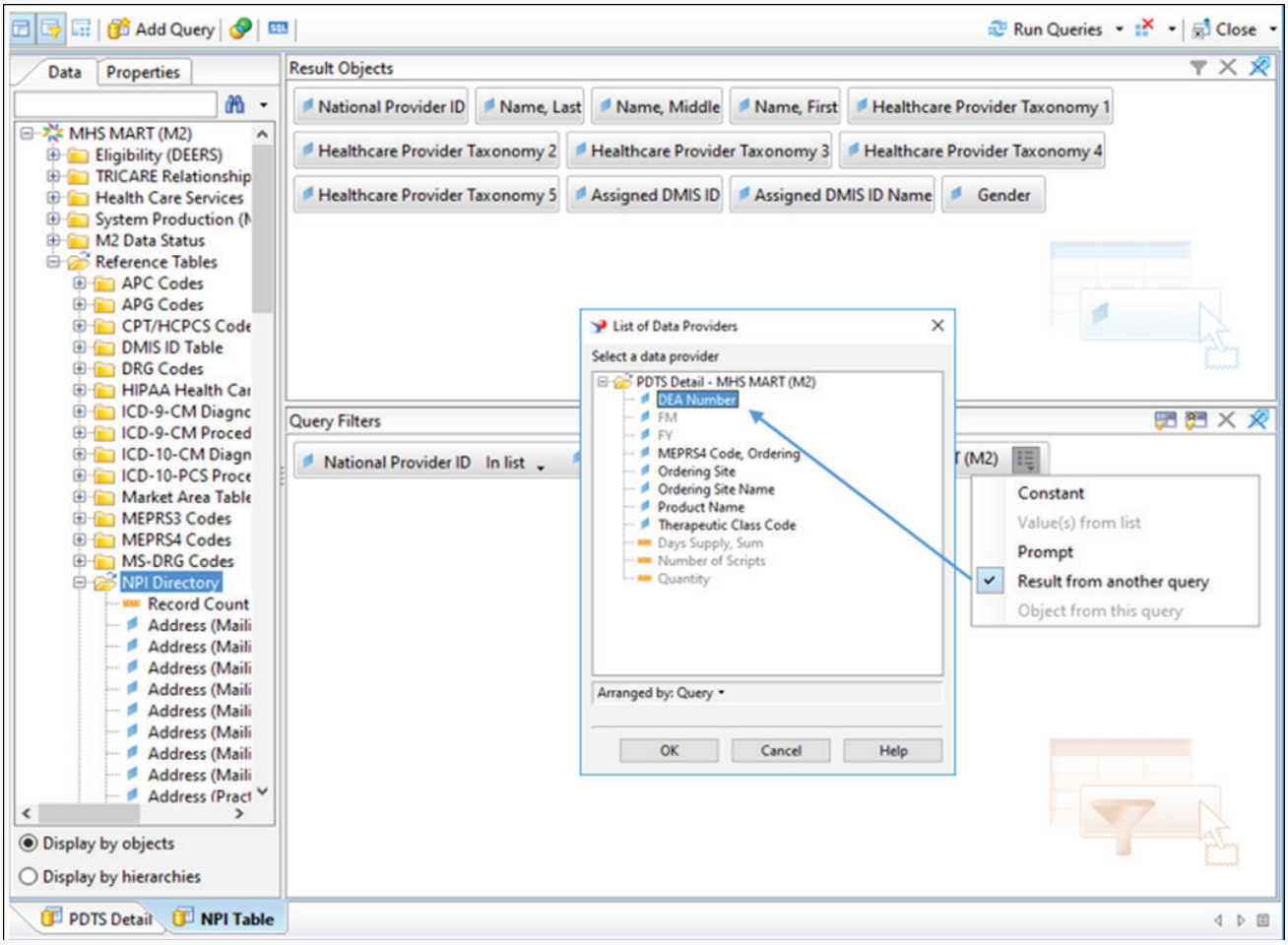


Next, select 'Edit Query' and 'Add Query', then navigate to the NPI Directory under the Reference Tables class. For result objects, select 'National Provider ID', 'Name, Last', 'Name, Middle', 'Name, First', 'Healthcare Provider Taxonomy 1-5', 'Assigned DMIS ID', 'Assigned DMIS ID Name', and 'Gender'.

EXAMPLE - LINKING

For query filters, include 'National Provider ID in list' and select 'Result from another query' and point to DEA Number (Figure 6).

Figure 6. NPI Table – Provider Information

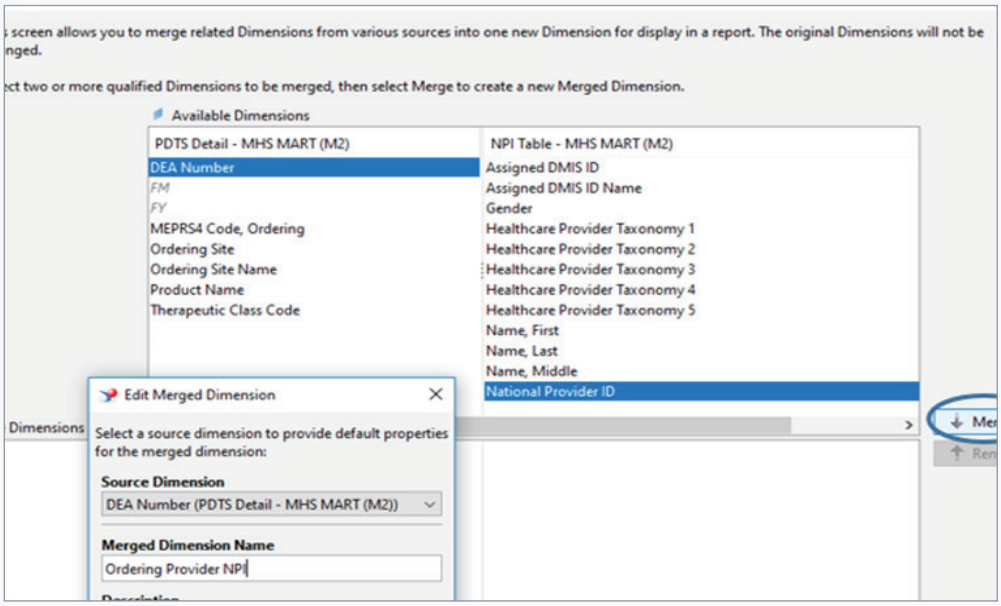


Select 'Run Query'.

Once data is retrieved, click on the 'Merge Dimensions' icon in the toolbar (Figure 7). Select 'DEA Number' and 'National Provider ID', then click 'Merge'. A pop up screen will appear – just select 'OK'. The Merged Dimensions name defaults to the first field selected under Available Dimensions. In this example, it is renamed to 'Ordering Provider NPI' using 'Edit Merged Dimension'. Select 'OK'.

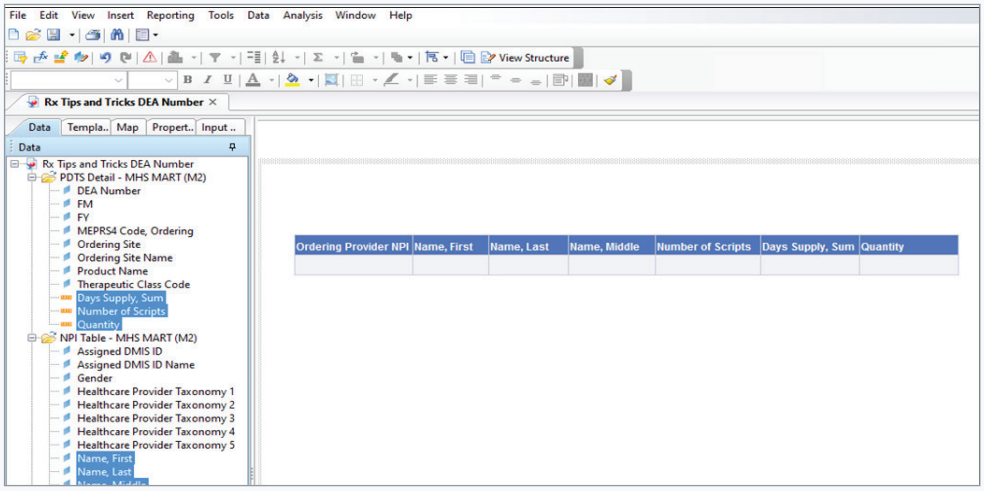
EXAMPLE - LINKING

Figure 7. Merging DEA Number and National Provider ID



Finally, right click on the last tab at the bottom of the report and select 'Insert Report'. Hold down the control key, and click on the desired objects in the data panel and drag them onto the page to create a table that shows the number of scripts, quantity and days supply of OxyContin by Ordering Provider NPI and his or her full name (Figure 8).

Figure 8. Quantity of OxyContin by Ordering Provider



Note: If a DEA Number is alphanumeric (usually starting with a letter), then it is an actual DEA Number and not an NPI; therefore, there will be no match for it in the NPI Directory. The most common alphanumeric DEA Numbers will start with 'B', which signifies a hospital or clinic.

KNOWLEDGE SOURCES

— WISDOM TRAINING OPPORTUNITIES

The WISDOM course provides guidance for MHS managers, data analysts, and policy makers in the use of MHS data in support of operational questions, management decisions, and corporate goals. Using a mix of instructive briefings and hands-on exercises, WISDOM strives to provide analysts and decision-makers with the tools needed to support data-driven analysis and decision-making—keys to successful organizational performance. WISDOM is the educational vehicle that can translate the widespread availability of corporate data through the MHS Management Analysis and Reporting Tool (M2) into improved MHS operations.

Working Information Systems to Determine Optimal Management (WISDOM)

The WISDOM course provides full instruction on the use of Business Objects and focused instruction on exploiting Microsoft Excel for analysis purposes. WISDOM also provides both an overview of different types of business and information systems used by the MHS (to include information systems, operational systems, corporate data warehouses and data marts), and specific detail on available data coming from those sources and accessible through the M2 data mart.

WISDOM participation is limited to individuals that currently have an M2 account and confirmed registration for the course. WISDOM is a 4-day class, held from Monday to Thursday; however, starting with the February 2017 session, the course is being extended from 4-days to 5-days. Specific dates for FY 2017 WISDOM classes[2] are noted below:

- San Antonio, TX – January 9-12, 2017
- San Diego, CA – February 6-10, 2017
- Arlington, VA – April 24-28, 2017
- San Antonio, TX – June 12-16, 2017
- San Antonio, TX – July 10-14, 2017
- Arlington, VA – September 18-22, 2017

The WISDOM schedule and additional information about course requirements are available online at http://www.health.mil/Military-Health-Topics/Technology/WISDOM-Training/Course-schedule. For questions regarding the WISDOM course or to register, please send an email to DHA NCR Dec Support List at dha.ncr.dec-support.list.dha-dec-sup-wisdom@mail.mil. Please note that the course also offers Continuing Medical Education (CME) credits.

2 In addition to the WISDOM in-class course, monthly one-hour Defense Collaboration Services (DCS) sessions are presented on various subjects. M2 blaster messages are sent out to all M2 users for each session. All DCS sessions are held at 9 a.m. and 5 p.m. Eastern Time usually on the last Wednesday of the month. Recordings of the WISDOM webinars are available on milTube at milSuite; search for 'WISDOM Webinar'.

IN THE NEXT ISSUE

The next issue of *Healthcare Analytics in Navy Medicine* will focus on optimization and variation. This issue will discuss some of the characteristics that can be associated with optimization efforts, particularly in an operational environment where variation is a component of the landscape. The issue will also highlight several statistical approaches and software that are used to evaluate these concepts.

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